The applicant noticed above applied to become registered with DEA to grow marihuana as bulk manufacturer subsequent to a 2016 DEA policy statement that provided information on how it intended to expand the number of registrations, and described in general terms the way it would oversee those additional growers. Before DEA completes the evaluation and registration process for applicants to grow marihuana, DEA intends to propose regulations in the near future that would supersede the 2016 policy statement and govern persons seeking to become registered with DEA to grow marihuana as bulk manufacturers, consistent with applicable law, as described in 84 FR 44920.


William T. McDermott,
Assistant Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–585]

Bulk Manufacturer of Controlled Substances Application: Patheon Pharmaceuticals, Inc.

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before April 24, 2020.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on December 23, 2019, Patheon Pharmaceuticals, Inc., 2100 E Galbraith Road, Cincinnati, Ohio 45237–1625 applied to be registered as a bulk manufacturer of the following basic class of controlled substances:

<table>
<thead>
<tr>
<th>Controlled substance</th>
<th>Drug code</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marihuana Extract</td>
<td>7350</td>
<td>I</td>
</tr>
<tr>
<td>Marihuana</td>
<td>7360</td>
<td>I</td>
</tr>
<tr>
<td>Tetrahydrocannabinols</td>
<td>7370</td>
<td>I</td>
</tr>
</tbody>
</table>

The Gamma Hydroxybutyric Acid will be produced during the process of converting gamma-butyrolactone into a new product for development. The company plans to manufacture the above-listed controlled substance as Active Pharmaceutical Ingredient (API) that will be further synthesized into dosage forms of a new product. No other activities for this drug code are authorized for this registration.


William T. McDermott,
Assistant Administrator.